MAY 16 2005

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Asclepion Laser Technologies GmbH • Göschwitzer Str. 51-52 • D-07745 Jena

Asclepion
Laser Technologies

510(k) SUMMARY

ASCLEPION LASER TECHNOLOGIES GmbH
MeDioStar XT Laser System

This 510(k) summary of safety and effectiveness for the Asclepion Laser Technologies GmbH MeDioStar XT Laser System is submitted in accordance with the requirements of 21 CFR 907.92 and follows Office of Device Evaluation Guidance concerning the organization and content of a 510(k) summary.

Applicant:	ASCLEPION LASER TECHNOLOGIES GmbH Goeschwitzer Str. 51-52 07745 Jena, Germany
Contact Person:	Mr Reinhard Thieme Quality Assurance and International Regulatory Affairs
Phone: Fax: e-mail:	+49 3641 220 211 +49 3641 220 322 reinhard.thieme@asclepion.com
Preparation Date:	March 23, 2005
Device Name:	MeDioStar XT Laser System
Common Name:	MeDioStar XT
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR 878.481
Equivalent Device:	MeDioStar H Laser Sytsem (with and without skin cooling system)
Device Description:	MeDioStar XT Laser System is a pulsed diode laser with a wavelength of 808µm. It consists a laser enclosure and optic delivery system (fiber bundle and handpiece).

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Intended Use:	The MeDioStar XT Laser System is intended to remove unwanted body hair and vascular lesions.
Comparison to:	The MeDioStar XT Laser System is substantially equivalent to the MeDioStar H Laser System (with and without skin cooling), with the same principles of operation, the same wavelength and essentially the same power range as the predicate device for the same indications for uses.
Nonclinical Performance Data:	None
Clinical Performance Data:	None
Conclusion:	The MeDioStar XT Laser System is another safe and effective device for the removal of unwanted body hair and the treatment of vascular lesions.
Additional Information:	None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2005

Mr. Reinhard Thieme
Quality Assurance and International Regulatory Affairs
Asclepion Laser Technologies GmbH
Goeschwitzerstrasse 51-52
Jena, Germany 07745

Re: K050900
Trade/Device Name: MeDioStar XT Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: April 26, 2005
Received: April 28, 2005

Dear Mr. Thieme:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K050960

Device Name: MeDioStar XT Laser System

Indications for Use:

The MeDioStar XT Laser System is intended to remove unwanted body hair and vascular lesions.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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